UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,428	03/26/2004	Sundeep Dugar	219002030500	2634

25225 7590 03/01/2006

MORRISON & FOERSTER LLP
12531 HIGH BLUFF DRIVE
SUITE 100
SAN DIEGO, CA 92130-2040

EXAMINER	
MCKENZIE, THOMAS C	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,428	DUGAR ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/27/04 & 3/3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to an application filed on 3/26/04. There are twenty claims pending. Claims 1-5 are compound claims. Claims 6 and 7 are composition claims. Claims 8-20 are method of using claims. The application concerns some 6,7-dihydro-5H-cyclopenta[d]pyrimidin-4-amine compounds, compositions, and uses thereof.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims parts of 1-4, drawn to 6,7-dihydro-5H-cyclopenta[d]pyrimidin-4-amine compounds among others, compounds of the formula (I) with all X = C and n = 2-5, classified in class 544, subclass 253.

II. Claims parts of 1-5, drawn to 7H-pyrrolo[2,3-d]pyrimidin-4-amine compounds, compounds of the formula (I) with one of X = N, 2 of X = C, and n = 3, classified in class 544, subclass 280.

III. Claims parts of 1-5, drawn to 7H-pyrrolo[3,4-d]pyrimidin-4-amine compounds, compounds of the formula (I) with one of X = N, 2 of X = C, and n = 3, classified in class 544, subclass 280.

IV. Claims parts of 1-5, drawn to 7H-pyrrolo[3,2-d]pyrimidin-4-amine compounds, compounds of the formula (I) with one of X = N, 2 of X = C, and n = 3, classified in class 544, subclass 280.

V. Claims parts of 1-5, drawn to 5,6-dihydropyrido[2,3-d]pyrimidin-4-amine among others, compounds of the formula (I) with one of X = N, 3 of X = C, and n = 4, classified in class 544, subclass 279.

VI. Claims parts of 1-5, drawn to purine compounds, compounds of the formula (I) with two of X = N, 1 of X = C, and n = 3, classified in class 544, subclass 277.

VII. Claims parts of 1-5, drawn to 3H-pyrazolo[4,3-d]pyrimidin-7-amine compounds, compounds of the formula (I) with two of X = N, 1 of X = C, and n = 3, classified in class 544, subclass 256.

VIII. Claims parts of 1-5, drawn to 1H-pyrazolo[3,4-d]pyrimidin-4-amine compounds, compounds of the formula (I) with two of X = N, 1 of X = C, and n = 3, classified in class 544, subclass 256.

IX. Claims parts of 1-5, drawn to 3H-[1,2,3]triazolo[4,5-d]pyrimidin-7-amine compounds, compounds of the formula (I) with X = N and n = 3, classified in class 544, subclass 254.

X. Claims parts of claim 1-5, drawn to thieno[2,3-d]pyrimidin-4-amine among others compounds, compounds of the formula (I) with one of X = S or O, two of X = C, and n = 3, classified in class 544, subclass 278.

XI. Claims parts of 1-5, drawn to all other compounds not listed above, compounds of the formula (I) with X = C, N, O, and/or S and n = 2-5, classified in class 540, subclass 552, among others.

XII-LXVI. Claims parts of 6-20, drawn to treatment of each one of the 55 specific diseases listed throughout claims 9-19, classified in class 514, subclass 211.08, among other.

3. Should Applicants elect Group XI then further restriction will be required as to the specific heterocyclic core Applicants wish to have examined and an election of species requirement will be made.

4. The inventions are distinct, each from the other because of the following reasons: the inventions are distinct, each from the other because of the following reasons: inventions I-XI are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different

design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the heterocyclic core of the structure given in claim 1 is the ring including variable X. This bicyclic ring is a mandatory feature and ranges in size from eight to eleven atoms with multiple possible heteroatoms. These multiple claimed rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I, II, V-VII, and IX-XII have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Groups II, V-VII, and IX-XII. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

5. Although Groups II-IV and XII &VIII are classified together these are patentably distinct ring systems, *i.e.* a reference against one ring would not be a reference against another. These will also raise separate issues of enablement for making and enablement for using. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

6. Should Applicants traverse the restriction requirement on the grounds that the different core rings are not patentably distinguishable, Applicants should identify such evidence now of record or submit any such evidence that shows the groups to be obvious variants. Such evidence may be used in a rejection under 35 USC 103(a) if the Examiner finds any of the Groups unpatentable over the prior art.

7. Inventions I-XI and XII-LXVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case congestive heart failure, one of the claimed uses may be treated with an ACE-Inhibitor like lisinopril (Prinivil, Zestril) or enalapril (Vasotec), drugs which prevent fluid build up like spironolactone (Aldactone)and beta-blockers like atenolol (Tenormin) and metoprolol (Lopressor, Toprol XL). Applicants admit their compounds have at least 55 distinct uses. thus, both prongs of the test are met.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in

accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

Conclusion

9. Information regarding the status of an application should be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). Please direct general inquiries to the receptionist whose telephone number is (703) 308-1235.

10. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (571) 272-0670. The FAX number for amendments is (571)

273-8300. The PTO presently encourages all applicants to communicate by FAX. The Examiner is available from 9:00am to 5:30pm, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, please contact James O. Wilson, SPE of Art Unit 1624, at (571)-272-0661.

Thomas C. McKenzie, Ph.D.
Primary Examiner
Art Unit 1624

TCMcK/me